

Applicant : Yousef Al-Abed
Appl. No. : 10/594,641
Filed : March 28, 2008

Remarks

Claims 1, 3, 9, 11 and 26-28 are pending in the subject application, claims 10 and 16 have been withdrawn from consideration, and Claims 1, 3, 9, 11, 27 and 28 have been rejected. By this amendment, Claim 1 has been amended to clarify applicants' invention. The amendments to Claim 1 are supported throughout the application including, for example, in the specification at page 32, lines 14 and 14-19, and Examples 1-23. Accordingly, the amendments to Claim 1 do not introduce new matter, and their entry is respectfully requested.

The various objections and rejections set forth in the Office Action are addressed below.

Objections

The Examiner objected to the title as not being descriptive. The title as been amended above. In view of this amendment, this objection is believed to be moot.

The Examiner also objected to the abstract for not being directed to the currently claimed invention. A replacement abstract is attached as Appendix 1. In view of this replacement abstract, this objection is also believed to be moot.

102(b) Rejection

Claims 1, 3, 9, 11, 27 and 28 were rejected under 35 U.S.C. 102(b) as anticipated by WO 01/64749 ("Kloetzer"). This rejection is respectfully traversed.

Kloetzer describes the use of an MIF antibody for treating arthritis, psoriasis, glomerulonephritis, septic shock, atopic dermatitis, and retinopathy associated with diabetes or lupus. Kloetzer does not teach a method of inhibiting the progression or development of type 1 diabetes in a mammal having type 1 diabetes or at risk for type 1 diabetes, as claimed. Accordingly, Kloetzer does not anticipate the claimed invention, and reconsideration and withdrawal of this rejection is respectfully requested.

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103 Rejections

Claims 1, 3, 9, 11 and 27 were rejected under 35 U.S.C. 103 as being unpatentable over Bojunga, et al. in view of Nishirira. This rejection is respectfully traversed.

Bojunga suggests that MIF may play a possible role in autoimmune-inflammatory events such as type-1 diabetes. In this regard, this potential role was based on preliminary studies in Bojunga in which it was shown that MIF-mRNA expression was elevated in the splenic lymphocytes of NOD mice in which diabetes was spontaneously induced. However, the MIF protein levels in the diabetic animals were less than in the normal controls. In another set of experiments, Bojunga evaluated the effect of MIF-protein treatment on diabetes in the NOD mice. While MIF treatment led to an increase in diabetes incidence over the untreated animals, Bojunga stated that this trend was not statistically significant. In summary, Bojunga suggests that MIF may be involved in diabetes. However, Bojunga does not provide any data which supports that an agent that inhibits a macrophage migration inhibitory factor (MIF) in the mammal, wherein the agent comprises a binding site of an antibody that binds specifically to MIF, would be effective in inhibiting the progression of type 1 diabetes in a mammal having type 1 diabetes or the development of type 1 diabetes in a mammal at risk for type 1 diabetes.

The addition of Nishirira does not remedy the deficiencies of Bojunga. Nishirira describes MIF as a target molecule in multiple sclerosis. Nishirira does not teach or suggest that an agent that inhibits a macrophage migration inhibitory factor (MIF) in the mammal, wherein the agent comprises a binding site of an antibody that binds specifically to MIF, would be effective in inhibiting the progression of type 1 diabetes in a mammal having type 1 diabetes or the development of type 1 diabetes in a mammal at risk for type 1 diabetes.

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For these reasons, the claimed invention is patentable over Bojunga in view of Nishirira. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claim 28 was rejected under 35 U.S.C. 103 as being unpatentable over Bojunga, et al. in view of Nishirira as applied to Claims 1, 3, 9, 11 and 27 above, and further in view of U.S. Patent No. 5,530,101 ("Queen"). This rejection is respectfully traversed.

As discussed above, the claimed invention is patentable over Bojunda in view of Nishirira. The addition of Queen does not remedy the deficiencies of Bojunda and Nishirira. Queen describes the production of humanized antibodies. Queen does not teach or that an agent that inhibits a macrophage migration inhibitory factor (MIF) in the mammal, wherein the agent comprises a binding site of an antibody that binds specifically to MIF, would be effective in inhibiting the progression of type 1 diabetes in a mammal having type 1 diabetes or the development of type 1 diabetes in a mammal at risk for type 1 diabetes.

For these reasons, the claimed invention is patentable over Bojunga, Nishirira and Queen. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Information Disclosure Statement

The Office Action included an acknowledge of consideration of the Information Disclosure Statement previously submitted by the applicant. However, certain citations were lined through for missing the authors and publication dates. A revised form PTO/SB/08b is attached to comply with the Examiner's request. It is noted that the citation for the Abstract now includes a list of the authors, while the citations for the Supplemental Partial European Search Report, the International Search Report and the International Preliminary Report on Patentability now include the publication or mailing dates of these documents. It is believed that a fee is not due in connection with

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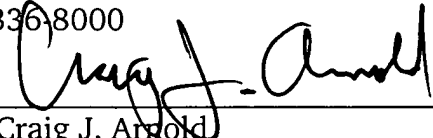
this revised form PTO/SB/08b. In any fee is required for submission and consideration of this form and the listed citations, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

No fee, other than the enclosed \$555 three month extension of time fee, is deemed necessary in connection with the filing of this Amendment. However, if this fee is in any way deficient, or if any additional fee is required to preserve the pendency of the subject application, authorization is hereby given to charge any such fee to Deposit Account No. 01-1785.

Respectfully submitted,

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